



GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

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WINDHOEK - 22 July 2019

No. 6958

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 202

2019

AMENDMENT OF REGULATIONS RELATING TO MEDICINES AND RELATED SUBSTANCES: MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

Under section 44 of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), after consultation with the Namibia Medicines Regulatory Council, I have amended the Regulations Relating to Medicines and Related Substances published under Government Notice No. 178 of 25 July 2008, as set out in the Schedule.

DR. K. SHANGULA
MINISTER OF HEALTH AND SOCIAL SERVICES

Windhoek, 8 July 2019

SCHEDULE

Definitions

1. In these regulations “the Regulations” means the Regulations Relating to Medicines and Related Substances published under Government Notice No. 178 of 25 July 2008 as amended by Government Notices No. 28 of 27 February 2015 and No. 316 of 31 December 2015.

Amendment of regulation 23 of Regulations

2. Regulation 23 of the Regulations is amended by the substitution for introductory sentence of subregulation (1) of the following introductory sentence:

“(1) Every prescription for a medicine or a schedule substance must be in print or written in block letters and signed in person by the authorised prescriber who wrote it, and must state -”.

Substitution of regulation 46 of Regulations

3. Regulation 46 of the Regulations is amended by the substitution for regulation 46 of the following regulation:

“Application for sale of an unregistered medicine in terms of section 27 of the Act

46. (1) An application for the sale of an unregistered medicine as contemplated in section 27(1) of the Act must be submitted to the Registrar in the form as set out in Annexure XXXVI, or XXXVI(A), in respect of veterinary medicine, to these regulations and must contain the information required therein.

(2) Authorisation to sell an unregistered medicine in terms of section 27(1) of the Act must be in the form as set out in Annexure XXXVII, or XXXVII(A), in respect of veterinary medicine, to these regulations.”.

Amendment of Annexures to Regulations

4. The Regulations are amended by the -

(a) substitution for Annexure XXXVI of the following Annexure:

**“ANNEXURE XXXVI
NAMIBIA MEDICINES REGULATORY COUNCIL**



MINISTRY OF HEALTH AND SOCIAL SERVICES

**APPLICATION FOR SALE OF UNREGISTERED MEDICINE
(Section 27 of the Act)
(Regulation 46)**

APPLICATION NUMBER

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

**PART A
PARTICULARS OF APPLICANT**

Name:

Qualifications:

Business address:

Postal address:

Telephone No: Fax No:

E-mail address:

**PART B
PARTICULARS OF THE MEDICINE TO BE SOLD**

Proprietary name:

Pharmacological classification:

Dosage form:

Dosage unit:

Approved names of the active pharmaceutical ingredient(s):

.....

.....

Strengths per dosage unit:

Descriptive name of biological medicine:

Country of origin:

Name of manufacturer:

Manufacturing site address:

.....

Is the medicine registered in the country of origin? (YES/NO)

Name other countries where the medicine is registered:
.....
.....

Has the manufacturer or representative applied for registration of the medicine in Namibia?
..... (YES/NO).

Indications for use of the medicine:

Explain in detail the purpose for which the medicine is required:

Patient details if the medicine is for an individual patient:

Name of patient:

Age: Sex:

Diagnosis:

Dosage:

Expected duration of treatment:

.....

Are there any registered alternatives of the medicine in Namibia? (YES/NO)

If “Yes” explain why the alternative can not be used?

.....

.....

.....

The undersigned hereby declares that all the information submitted above is true and correct, and that a full report on the use of this medicine will be provided to the Namibia Medicines Regulatory Council on completion of the treatment.

.....

Signature of applicant

.....

Name in block letters

.....

Date of application”.

(b) insertion after Annexure XXXVI of the following Annexure:

“ANNEXURE XXXVI(A)

NAMIBIA MEDICINES REGULATORY COUNCIL



MINISTRY OF HEALTH AND SOCIAL SERVICES

**APPLICATION FOR SALE OF UNREGISTERED MEDICINE:
VETERINARY MEDICINE**

(Section 27 of the Act)
(Regulation 46)

APPLICATION NUMBER

--

TO:
 The Registrar of Medicines
 Namibia Medicines Regulatory Council
 Ministry of Health and Social Services
 Private Bag 13198
 WINDHOEK

**PART A
PARTICULARS OF APPLICANT**

Name:
Qualifications:
Business address:
Postal address:
Telephone No: Fax No:
E-mail address:

PARTICULARS OF PRESCRIBING VETERINARIAN

Name: Qualification/s:

Namibia Veterinary Council registration number:

Practice/Clinic/Hospital details:

Name

Physical address:

Registration number:

Postal address:

Telephone No: E-mail address:

**PART B
PARTICULARS OF THE MEDICINE TO BE SOLD**

Proprietary name:

Pharmacological classification:

Dosage form:

Approved names of the active pharmaceutical ingredient(s):

.....

.....

Strengths per dosage unit:

Descriptive name of biological medicine:

Country of origin:

Name of manufacturer:

Manufacturing site address:

.....

Is the medicine registered in the country of origin? YES / NO

Name other countries where the medicine is registered:
.....

Has the manufacturer or representative applied for registration of the medicine in Namibia?
YES / NO

If the medicine is not registered in any country, what is the stage of development of the medicine:

.....

Indications for use of the medicine:

.....

Purpose for which the medicine is required: Treatment / Research / Sponsorship / Other

Explanation:

.....

Owner Details

Name:

Physical Address (farm)

Group patients' details: Herd or Group / Individual / Other:

If Other, specify clearly:

Herd or group identification attached: Yes / No:

Species:

Individual patient details:

Patient name/ID number: Species:

Age: Sex:

Diagnosis and Treatment details:

Diagnosis:

Dosage:

Expected duration of treatment:

.....

Are there any alternative veterinary medicines registered in Namibia with due consideration to the same species, formulation, dosage form and strength? YES / NO

If "Yes" explain why the alternative medicine cannot be used.

.....

.....

The undersigned hereby declares that all the information submitted above is true and correct.

If an abnormal medicinal reaction / side effect is observed, this should be reported to the Namibia Medicines Regulatory Council.

.....

Signature of applicant

.....

Name in block letters

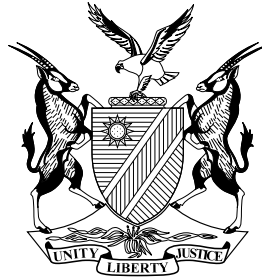
.....

Date of application".

(c) substitution for Annexure XXXVII of the following Annexure:

“ANNEXURE XXXVII

NAMIBIA MEDICINES REGULATORY COUNCIL



MINISTRY OF HEALTH AND SOCIAL SERVICES

**AUTHORISATION FOR THE SALE OF AN UNREGISTERED MEDICINE IN
TERMS OF SECTION 27 OF THE ACT
(Regulation 46)**

The Namibia Medicines Regulatory Council hereby authorises in terms of section 27 of the Act the use of the unregistered medicine(s) listed below:

Name of medicine:

Dosage form:

Strength per dosage unit:

Quantity:

Manufacturer:

Manufacturing site address

Name of patient:

Age: Sex:

Diagnosis:

Dosage and duration of treatment:

Clearance no:

Name and address of hospital:

Name of medical practitioner: (Applicant):

.....
Registrar of Medicines

.....
Date”.

(d) insertion after Annexure XXXVII of the following Annexure:

“ANNEXURE XXXVII(A)

NAMIBIA MEDICINES REGULATORY COUNCIL



MINISTRY OF HEALTH AND SOCIAL SERVICES

**AUTHORISATION FOR THE SALE OF AN UNREGISTERED MEDICINE IN
TERMS OF SECTION 27 OF THE ACT: VETERINARY MEDICINE
(Regulation 46)**

The Namibia Medicines Regulatory Council hereby authorises in terms of section 27 of the Act the use of the unregistered medicine(s) listed below:

Name of medicine:

Dosage form

Strength per dosage unit:

Quantity:

Manufacturer:

Species: Patient / Group / Herd:

Age: Sex:

Diagnosis:

Dosage and duration of treatment:

Clearance no:

Name and address of prescribing veterinarian:

Name and address of applicant:

.....
Registrar of Medicines

.....
Date”.